

Message

From: Daniels, Rhys G. [daniels@khlaw.com]
Sent: 7/23/2021 7:55:31 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Berger, Tom C. [Berger@khlaw.com]; Price, Amanda [price@khlaw.com]
Subject: RE: Report Request - P-15-04X2-04X7 and P-15-05X5-05X8
Attachments: ATT00001.txt

Afternoon Jeff,

In response to our previous request for the sanitized engineering and health reports for each of the two consolidated PMNs and the single Standard Review Report covering the two consolidated PMNs, you indicated that the reports have not been updated since they were sent to the submitter back in 2016. However, the submitter has notified us that it cannot find the report in its files. Nor can it find any record of having received the reports. Accordingly, we again request that sanitized copies of these reports, which already having been provided to the submitter must exist, now be added to CDX so that the submitter can access them.

At this time the submitter is not asking EPA to perform a new review. Rather, the submitter needs the reports to independently assess EPA MOE/Fold Factor calculations and then determine if the information in the two submitted toxicological studies would support a request to modify or revoke the consent order for the subject PMNs.

Thanks,

Rhys G. Daniels, Ph.D.

Staff Scientist

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, April 16, 2021 12:28 PM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: Report Request - P-15-04X2-04X7 and P-15-05X5-05X8

Rhys,

I cannot locate where your listed in the PMN as an Authroized official. I did fax 3rd party sanitized documents eng, exp, standard review to the technical contact during the review. A new contact was to be added (Deb) to the PMN but that never happened and my last communication went to only contact in the PMN and it is listed in CDX for you to review of the inhalation studies. If the contact would like me to sanitized documents we now will put them directly into CDX (with the respective consolidated set) and no longer email them. Can you Modify the two consolidated PMNs with the updated Contact information and I can Sanitize the Engineering report, exposure report and the Standard review Report. Sine they came in as two different submission there will be an exposure report and engineering report for the respective submissions. However the Standard review is for both sets.

Thanks

Jeff

564-9042

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchemicals/>

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From: Daniels, Rhys G. <daniels@khlaw.com>

Sent: Friday, April 16, 2021 11:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Berger, Tom C. <Berger@khlaw.com>

Subject: Report Request - P-15-04X2-04X7 and P-15-05X5-05X8

Morning Jeff,

In January 2018, our client entered into a TSCA consent order with EPA covering 10 PMN substances, designated as P-15-04X2 through P-15-04X7 and P-15-05X5 through P-15-05X8. As stipulated in the Consent Order, our client submitted draft final reports for two toxicity studies to EPA in July 2019.

In connection with modification or revocation of the TSCA Consent Order, the submitter has requested that we obtain copies of the original and any updated, post-study submission versions of the Initial Review Engineering Reports, Structure-Activity Reports, Health Reports, and any other reports the Agency prepared during review on the potential toxicity of and exposure to the PMN substances.

Because we are listed as technical contacts in the original PMNs, we request EPA to provide the sanitized documents directly to us.

As always, please let us know if you have any questions concerning this request.

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